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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,693	11/07/2000	Se-Jin Lee	JHU 1120-15	2065

28213 7590 08/28/2007  
DLA PIPER US LLP  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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08/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/708,693

Applicant(s)

LEE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,9-11,15,19,22,26-29,31-33,37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 41 is/are allowed.
- 6) ☒ Claim(s) 1,9-11,15,19,22,27-29,31-33,37,39,40,42 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/07 (after final amendment dated 4/9/07) has been entered.

Claims 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, 39-43 are pending and under consideration.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, 39-40, and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,369,201 B1).

This rejection is maintained for reasons of record.

Particular embodiments embraced by claim 1 are substantially purified peptides consisting of about amino acids 1-20 of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, or 18 (the promyostatin signal peptide domain). These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 33 and 37 are substantially purified peptides consisting of amino acids 20-262 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, or 18 or consisting of about amino acids 20-263 of SEQ ID NOS: 4 or 6 (the promyostatin prodomain). These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 19, 22, and 42-43 are substantially purified peptides consisting of about amino acids 268-375 of SEQ ID NOS: 4 or 6 or consisting of amino acids 267-374 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, or 18, (the promyostatin myostatin domain). These concepts are not disclosed by parent application 09/124,180, particularly with the newly introduced activity limitation.

The parent application does not disclose nor contemplate as the invention a polynucleotide encoding a peptide limited to the promyostatin signal peptide domain, promyostatin prodomain or promyostatin myostatin domain having the newly introduced activity limitations as set forth in the claims. The claims embrace these smaller domains and are not limited to the full length polypeptides. Applicant has not pointed to any page and line number of parent application 09/124,180 setting forth these concepts. Page 44 does not disclose nor contemplate isolated polynucleotides encoding these smaller portions of the polypeptide as being the intended invention.

As such, benefit to the filing date of parent application 09/124,180 is denied for all claims. The effective filing date for these claims is considered to be 27 July 2000.

Barker et al. is valid prior art against the instant claims as this application was filed on 18 February 1999.

Barker et al. discloses the full length sequences for human, murine, rat, chicken, baboon, bovine, porcine, ovine, and turkey promyostatin polypeptides. Barker's SEQ ID NOS: 29, 27, 28, and 30 corresponding directly to instant SEQ ID NOS: 4, 6, 2, and 10, respectively. Barker's SEQ ID NOS: 31-34 have a conservative substitution in a single position with respect to instant

SEQ ID NOS: 12, 14, 16, and 8, respectively. Barker's SEQ ID NO: 35 has two mismatches to instant SEQ ID NO: 18. Particular fragments of these polypeptides are also disclosed. See at least Figure 1A-1D and column 3, lines 25-45. Note that none of the mismatches occurs in the promyostatin myostatin domain and only one mismatch (for SEQ ID NO: 18) occurs in the promyostatin signal peptide domain. However, as the mismatch in SEQ ID NO: 18 is at amino acid three, this is considered to be within the claim limitation of "about 1-20." Polynucleotides encoding the proteins, expression vectors, and isolated host cells are disclosed.

This disclosure anticipates the instant claims as the claims all use "comprising" or open language and include the full length sequences as well as the fragments disclosed by Barker et al.

As set forth in the Advisory Action dated 4/30/07, applicant has argued they are entitled to priority of the 09/124,180 application and pointed to Figures 6A-B and 12A, pages 44-47, 50, and 54, and Example 5. This is not agreed with. None of these sections provides support for the breadth and all limitations of the pending claims. There is no contemplation in any of these sections for a polynucleotide encoding a promyostatin signal peptide alone. There is no contemplation in any of these sections for a polynucleotide encoding a promyostatin myostatin domain alone. There is no contemplation in any of these sections for a polynucleotide encoding a promyostatin prodomain alone. A disclosure of where domains are located is not contemplation of a polynucleotide encoding that particular domain alone. Page 50 and Figure 12A disclose a particular murine vector construct. The claims are not so limited. Example 5 is directed to a particular murine fusion protein. The claims are not so limited. These specific examples do not provide support or contemplation of the generic concepts present in the instant

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claims. Applicant is denied benefit of this date and Barker et al. remains valid prior art against the claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Marianne P. Allen*

Marianne P. Allen  
Primary Examiner  
Art Unit 1647

*8/23/07*

mpa